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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/005,549	10/29/2001	Michael A. Bowen	D0034 NP	8020

23914 7590 05/18/2005

STEPHEN B. DAVIS
BRISTOL-MYERS SQUIBB COMPANY
PATENT DEPARTMENT
P O BOX 4000
PRINCETON, NJ 08543-4000

EXAMINER	
PROUTY, REBECCA E	
ART UNIT	**PAPER NUMBER**
1652	

DATE MAILED: 05/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/005,549	BOWEN ET AL.	
	Examiner	Art Unit	
	Rebecca E. Prouty	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 March 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17* is/are pending in the application.

4a) Of the above claim(s) *6-17* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *1-05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

A request for continued examination under 37 CFR 1.114 was filed in this application after appeal to the Board of Patent Appeals and Interferences, but prior to a decision on the appeal. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 3/3/05 has been entered.

Claim 18 has been canceled. Claims 1-17 are at issue and are present for examination.

Claims 6-17 remain withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made without traverse in the response filed 7/9/03.

Applicants' arguments filed on 3/3/05, have been fully considered but are not deemed to be persuasive to overcome the rejection previously applied.

Claims 1-5 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility.

Applicant have asserted utility for the polypeptide of SEQ ID NO:2 encoded by the claimed isolated polynucleotide of SEQ ID

NO:1 as a ubiquitin conjugating enzyme or for "diagnosis, treatment or prevention of cancers and tumors, or immune, lymphoproliferative, or neurodegenerative disorders". However, the asserted utilities are not specific and substantial. While the specification includes sufficient evidence for the skilled artisan to believe that the protein of SEQ ID NO:2 is a ubiquitin conjugating enzyme, the specification fails to assert what protein(s), SEQ ID NO:2 conjugates ubiquitin to. Ubiquitin conjugating enzymes comprise a highly diverse group of proteins which conjugate ubiquitin to a wide variety of different proteins with different enzymes having an enormous diversity in the specificity of substrates utilized (See for example Hershko et al). As ubiquitin conjugating enzymes are such a large diverse family of enzymes, a mere disclosure that a protein is a ubiquitin conjugating enzyme without a more specific recitation of what type of ubiquitin conjugating enzyme (i.e., what protein(s) is/are conjugated) is insufficient to provide a substantial utility as the skilled artisan would require further research to identify or reasonably confirm a real world context of use. The specification also lists a general use for the polypeptides encoded by the claimed polynucleotides as useful for "diagnosis, treatment or prevention of cancers and tumors, or immune, lymphoproliferative, or neurodegenerative disorders".

However, there is no information that links the use of the polypeptide of SEQ ID NO:2 or the polynucleotide of SEQ ID NO:1 and its variants to any specific disease state. Thus the asserted utility of the claimed polynucleotides and its variants is not substantial or specific. Further, while the specification discloses that SEQ ID NO:1 and its fragments will be used to generate probes, that is not a utility specific to the claimed polynucleotide sequence. For all the reasons detailed above, the claimed polynucleotides lack, a specific, substantial and credible utility

Applicants argue that the present invention provides a novel polynucleotide encoding a ubiquitin conjugating enzyme homologue, which was isolated from activated human T-cells and was discovered to be upregulated upon stimulation of Jurkat-line T cells and human peripheral blood T lymphocytes with antibodies directed against the CD3 and CD28 cell surface antigens. Applicants state that the discovery that the claimed polynucleotide is upregulated after stimulation of these cells strongly suggests that this gene is critical for either the activation of the T-cell or for the stimulation of immune processes downstream of T-cell activation and that it is possible that the claimed polynucleotide plays a role in the stimulation of transcription of other cytokines, chemokines or

effector molecules critically involved in an immune response. All of these data taken together suggest that the claimed polynucleotide may play a role in autoimmune disease, and that this utility is understood and appreciated by the those of skill in the art. Accordingly, the present invention clearly has specific and substantial utility in satisfaction of Section 101.

Applicants arguments are not persuasive because none of the above provides even an assertion of a utility that can be considered to be specific and substantial. Neither applicants response nor the specification define what use a skilled artisan would believe a polynucleotide that is upregulated upon stimulation of T-cells with antibodies to the CD3 and CD28 cell surface antigens has. Applicants response merely speculates as to potential processes in which the claimed polynucleotide **might** play a role without any definition of which of these (if any) is actually correct. The specification fails to teach how a skilled artisan uses the claimed polynucleotide to diagnosis, treat or prevent any cancer or tumor, or any immune, lymphoproliferative, or neurodegenerative disorders as it fails to clearly link the claimed polynucleotide to any such disorder. While it is true that some ubiquitin conjugating enzymes and polynucleotides which are upregulated upon T-cell activation are known to be involved in cancers, immune disorders,

lymphoproliferative disorders, and neurodegenerative disorders, not all ubiquitin conjugating enzymes and polynucleotides which are upregulated upon T-cell activation have any role in these processes and there is no evidence of record that the claimed polynucleotide is involved in ANY disease state and it is just as likely that it is not. In view of the failure of the specification to provide a correlation of the claimed polynucleotide to a specific disease state and the necessary guidance for using the claimed polynucleotide to diagnose and treat a specific disorder, significant further research would be necessary for the skilled artisan to use the claimed polynucleotides in a real world context, and thus the asserted utility is not substantial.

Applicants argue that as SEQ ID NO:2 clearly sets forth a ubiquitin conjugating enzyme (as acknowledged by the Examiner), that this is sufficient to establish Section 101 utility of the invention. The fact that the class of compounds to which the invention belongs is diverse is not relevant in determining if the present invention has specific and substantial utility in accordance with the PTO's interpretation of Section 101. This is not persuasive because the diversity of the family is highly relevant in the instant case because merely placing a new compound into the family of ubiquitin-conjugating enzymes is

insufficient to tell a skilled artisan how to use the new compound. While the skilled artisan would be aware that the new enzyme would be useful for conjugating ubiquitin to some unknown protein, without knowledge of what the enzyme would conjugate ubiquitin to, one could not use it.

All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated

from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rebecca E. Prouty whose telephone number is 571-272-0937. The examiner can normally be reached on Tuesday-Friday from 8 AM to 5 PM. The examiner can also be reached on alternate Mondays

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can be reached at (571) 272-0928. The fax phone number for this Group is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Rebecca Prouty
Primary Examiner
Art Unit 1652